Breathe Easier Alliance of Alabama

(BEAA)



harm reduction for adults via personal vaporizers which are shown to reduce the morbidity and mortality The Breathe Easier Alliance of Alabama is an advocacy group focused on legislation affecting tobacco associated with smoking.

Who We Are

- ceptional accountability and high standards are vital to gaining acceptance of those who be-BEAA membership is comprised of responsible business owners who understand that exlieve the industry is driven or influenced by big tobacco.
- The vaping industry in Alabama is comprised of over 300 small businesses that employ over 2000 people, all while facilitating a reduced-harm alternative for millions of tobacco
- BEAA members alone include well over 50 small vape related businesses, employing over 250 employees utilizing some 50,000 square feet of retail space with taxable sales totaling over \$25,000,000.00.
- and become a vibrant and multibillion-dollar industry that constantly strives to be more and eighty hours a week for something we feel passionately about. We have grown organically corporations with endless resources. I as well as many others have risked our homes, re-The vapor products industry is the epitome of the American Dream; We are not huge entrepreneurs and visionaries on which this industry has thrived. We work seventy and tirement and everything that we have for a chance at the American Dream. more creative and innovative in tobacco harm reduction.

Pre-Market Tobacco Approval Application Process

- The FDA has estimated the cost of applying for a Pre-Market Tobacco Approval for each vapor product at 5,000 hours and \$333,554.
- completing an application to be more like \$3.3 million, and could be more like \$33 • These estimates are also totally unrealistic, as experts estimate the actual cost of million per SKU
- The cost alone will preclude any small or even reasonable sized company from applying thus leaving the market wide open to big tobacco and effectively decimating the small business owners.
- nomic impact on "small entities". At no time do they appear to consider the benefits retail space rental and most importantly offering a better alternative to combustible these small businesses bring to their communities by way of employment, sales tax, • The FDA has openly admitted that the proposed rule would have a significant ecocigarettes.

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FUA Deeming Regulations

- The FDA admits that not regulating new products like e-cigarettes may induce peo-"stringency". So not regulating would imply a benefit and the proposed rule will ple to switch to products that the FDA do not regulate at all or with the same
- rule" These benefits will be reduced by the simple fact that electronic cigarettes are In the RIA Benefit Analysis, FDA anticipates that "the largest benefit of the proposed reduction in the use of combustible tobacco products deemed under this proposed provisions would be the improvements in health and life expectancy resulting from not combustible tobacco products and provide a safer alternative.
- In section 2(b) of the RIA, "Electronic Cigarettes and Other Non-combustible, Novel rettes in this proposed rule are unknown and therefore cannot be quantified (page Tobacco Products" FDA plainly states: "The benefits of including electronic ciga-

Conclusion

- Ultimately, the FDA not having regulatory power over the electronic cigarette industry would regulation however being lumped together with combustible cigarettes does not allow for our unique industry to flourish nor does it recognize the significant health benefits to consumers be ideal for business owners and consumers alike. We are not against reasonable, rational having access to a variety of tobacco harm reduction options and devices.
- Should the FDA move forward with full PMTA, we would hope the industry would have a minimum of 2 to 3 years to comply with requirements, once the requirements are clearly defined.
 - nate, or ensure they could comply (if it were ever available to them). Please support H.R. Bill 2007 guaranteeing Substantial Equivalence (SE) Reports cannot be submitted to the FDA, creating a de-facto ban of >99.9% of the vapor product manufacturers in the US. Further the SE process is opaque and entirely arbitrary, denying participants the ability to pre-plan, coordi-Only 2-3 companies marketed vapor products before the grandfather date of February 15,
- Our industry has been on notice for over a year that these regulations are coming and we have been waiting to find out what e-cigarette-specific PMTA requirements are so that we may prepare. There is a considerable difference between expedited EU-like requirements, which take months to prepare for, vs, full PMTA, which takes years.